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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,554	04/14/2004	Ragupathy Madiyalakan	AREX-P03-005	6247

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EXAMINER	
BRISTOL, LYNN ANNE	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/824,554	MADIYALAKAN ET AL.	
	Examiner	Art Unit	
	Lynn Bristol	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6,9-16 and 22-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1, 3-6, 9-16, and 22-30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 2, 7, 8, and 17-21 were cancelled, Claims 1, 4-6,15, 16 and 22 were amended, and new Claims 26-30 were added by Preliminary Amendment of June 14, 2004. Claims 1, 3-6, 9-16, and 22-30 are pending in the present application.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 3, 4 in part, 5, 6, 9-11, and 26-30, drawn to a method of diagnosing the efficacy of antibody mediated immunotherapy by measuring the level of an antibody that binds to a xenotypic antibody. If Group I is elected claim 4 will be examined to the extent this claim reads on the CA125 antigen, classified in class 435, subclass 7.23.

II. Claims 1, 3, 4 in part, 5, 6, 9-11, and 26-30, drawn to a method of diagnosing the efficacy of antibody mediated immunotherapy by measuring the level of an antibody that binds to a xenotypic antibody. If Group II is elected claim 4 will be examined to the extent this claim reads on the MUC-1 antigen, classified in class 435, subclass 7.92.

III. Claims 1, 3, 4 in part, 5, 6, 9-11, and 26-30, drawn to a method of diagnosing the efficacy of antibody mediated immunotherapy by measuring the level of an antibody that binds to a xenotypic antibody. If Group III is elected claim 4 will be examined to the extent this claim reads on the prostate specific antigen, classified in class 435, subclass 7.92.

IV. Claims 12-14, 15 in part, 16, drawn to a method of diagnosing the efficacy of antibody mediated immunotherapy by measuring the level of an anti-idiotypic antibody that binds to a xenotypic antibody. If Group IV is elected claim 15 will be examined to the extent this claim reads on the CA125 antigen, classified in class 435, subclass 7.23.

V. Claims 12-14, 15 in part, 16, drawn to drawn to a method of diagnosing the efficacy of antibody mediated immunotherapy by measuring the level of an anti-idiotypic antibody that binds to a xenotypic antibody. If Group V is elected claim 15 will be examined to the extent this claim reads on the MUC-1 antigen, classified in class 435, subclass 7.92.

VI. Claims 12-14, 15 in part, 16, drawn to drawn to a method of diagnosing the efficacy of antibody mediated immunotherapy by measuring the level of an anti-idiotypic antibody that binds to a xenotypic antibody. If Group VI is elected claim 15 will be examined to the extent this claim reads on the prostate specific antigen, classified in class 435, subclass 7.92.

VII. Claims 22-25, drawn to a method of diagnosing the efficacy of antibody mediated immunotherapy by measuring the level of a T cell response, classified in class 435 subclass 7.1.

3. The inventions are distinct, each from the other because of the following reasons:

The methods of Inventions I-VII differ in the method objectives, method steps and parameters and in the reagents used. Inventions I-III recite a method of measuring the level of an antibody to different and distinct antigens; Invention IV-VI recite a method of

measuring the level of an anti-idiotypic antibody wherein the antibody is directed to different and distinct antigens; and Invention VII recites a method of measuring the increase in antigen-specific T cell response after administration of an antibody against the antigen. Methods I-III differ from Methods IV-VI in that the method does not require measuring an anti-id response, the method can measure an antibody to the Fc region. Method VII differs from Methods I-III and Methods IV-VI in that the method does not require measuring an antibody response, the method can measure the level of a T cell response. The examination of all groups would require different searches in the U.S. PATENT shoes and the scientific literature and would require the consideration of different patentability issues. Thus Inventions I-VII are separate and distinct in having different method objectives, method steps and parameters and in the reagents used and are patentably distinct.

4. If Groups I-VI are elected then an election of species is required. This application contains claims directed to the following patentably distinct species of the claimed invention:

Species a: cancer

Species b: inflammatory disease

Species c: bacterial infection

Species d: parasitic infection

Species e: viral infection

The species a-e do not share a common utility nor do they have a substantial structural feature common amongst them. Each of the disorders has a different etiology; involves a different arm of the immune response (e.g., humoral and/or cellular and/or inflammatory); has a different clinical course and outcome(s) that are influenced by endogenous autocrine and paracrine effects of cytokines, growth factors, hormones, etc.; and each disorder is recognized as being managed by different therapeutic approaches. One could consult any medical textbook to appreciate the different evaluation, clinical work-up and recommended clinical management for each of these separate and distinct disorders. The species are not obvious variants or overlapping, thus to search the species together would present a search burden on the Examiner due to the extensive databases of non-patent literature and because searching the databases is not co-extensive.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 12 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different classifications, restriction for examination purposes as indicated is proper.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER